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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/466,778	12/20/99	HASTINGS G	PF487

HM12/0821

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EXAMINER	
EINSMANN,J	
ART UNIT	**PAPER NUMBER**
1655	6

DATE MAILED: 08/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/466,778	HASTINGS ET AL.	
	Examiner	Art Unit	
	Juliet C. Einsmann	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 14 and 15, drawn to nucleic acids related to WF-HABP (SEQ ID NO: 1), vectors, host cells and methods for the expression of host cells, classified in class 536/23.1, 435/320.1, 435/325.5, and 435/69.1.

II. Claims 11-12, drawn to isolated polypeptides related to WF-HABP (SEQ ID NO: 2), classified in class 530 subclass 350.

III. Claims 13 and 16, drawn to an antibody that binds specifically to polypeptides related to WF-HABP (SEQ ID NO: 2), classified in class 530, subclass 387.1.

IV. Claims 17, drawn to methods for preventing, treating, or ameliorating a medical condition using polypeptides related to WF-HABP (SEQ ID NO: 2), classified in class 514, subclass 2.

V. Claim 17, drawn to methods for preventing, treating or ameliorating a medical condition using polynucleotides related to WF-HABP (SEQ ID NO: 1), classified in class 514, subclass 44.

VI. Claim 18, drawn to methods of diagnosing a pathological condition by determining a mutation in polynucleotides related to WF-HABP (SEQ ID NO: 1), classified in class 435, subclass 6.

VII. Claim 19, drawn to methods of diagnosing a pathological condition by determining the level of expression of polypeptides related to WF-HABP (SEQ ID NO: 2), classified in class 435, subclass 4.

VIII. Claim 20, drawn to a method for identifying a binding partner to polypeptides related to WF-HABP (SEQ ID NO: 2), classified in class 530, subclass 412.

IX. Claims 21 and 22, drawn to methods for identifying compounds capable of enhancing or inhibiting a cellular response induced by full length WF-HABP (SEQ ID NO: 2), classified in class 435, subclass 4.

X. Claims 1-10, 14 and 15, drawn to nucleic acids related to WF-HABP (SEQ ID NO: 4), vectors, host cells and methods for the expression of host cells, classified in class 536/23.1, 435/320.1, 435/325.5, and 435/69.1.

XI. Claims 11-12, drawn to isolated polypeptides related to WF-HABP (SEQ ID NO: 5), classified in class 530 subclass 350.

XII. Claims 13 and 16, drawn to an antibody that binds specifically to polypeptides related to WF-HABP (SEQ ID NO: 5), classified in class 530, subclass 387.1.

XIII. Claims 17, drawn to methods for preventing, treating, or ameliorating a medical condition using polypeptides related to WF-HABP (SEQ ID NO: 5), classified in class 514, subclass 2.

XIV. Claim 17, drawn to methods for preventing, treating or ameliorating a medical condition using polynucleotides related to WF-HABP (SEQ ID NO: 4), classified in class 514, subclass 44.

XV. Claim 18, drawn to methods of diagnosing a pathological condition by determining a mutation in polynucleotides related to WF-HABP (SEQ ID NO: 4), classified in class 435, subclass 6.

XVI. Claim 19, drawn to methods of diagnosing a pathological condition by determining the level of expression of polypeptides related to WF-HABP (SEQ ID NO: 5), classified in class 435, subclass 4.

XVII. Claim 20, drawn to a method for identifying a binding partner to polypeptides related to WF-HABP (SEQ ID NO: 5), classified in class 530, subclass 412.

XVIII. Claims 21 and 22, drawn to methods for identifying compounds capable of enhancing or inhibiting a cellular response induced by full length WF-HABP (SEQ ID NO: 5), classified in class 435, subclass 4.

XIX. Claims 1-10, 14 and 15, drawn to nucleic acids related to OE-HABP (SEQ ID NO: 7), vectors, host cells and methods for the expression of host cells, classified in class 536/23.1, 435/320.1, 435/325.5, and 435/69.1.

XX. Claims 11-12, drawn to isolated polypeptides related to OE-HABP (SEQ ID NO: 8), classified in class 530 subclass 350.

XXI. Claims 13 and 16, drawn to an antibody that binds specifically to polypeptides related to OE-HABP (SEQ ID NO: 8), classified in class 530, subclass 387.1.

XXII. Claims 17, drawn to methods for preventing, treating, or ameliorating a medical condition using polypeptides related to OE-HABP (SEQ ID NO: 8), classified in class 514, subclass 2.

XXIII. Claim 17, drawn to methods for preventing, treating or ameliorating a medical condition using polynucleotides related to OE-HABP (SEQ ID NO: 7), classified in class 514, subclass 44.

XXIV. Claim 18, drawn to methods of diagnosing a pathological condition by determining a mutation in polynucleotides related to OE-HABP (SEQ ID NO: 7), classified in class 435, subclass 6.

XXV. Claim 19, drawn to methods of diagnosing a pathological condition by determining the level of expression of polypeptides related to OE-HABP (SEQ ID NO: 8), classified in class 435, subclass 4.

XXVI. Claim 20, drawn to a method for identifying a binding partner to polypeptides related to OE-HABP (SEQ ID NO: 8), classified in class 530, subclass 412.

XXVII. Claims 21 and 22, drawn to methods for identifying compounds capable of enhancing or inhibiting a cellular response induced by full length OE-HABP (SEQ ID NO: 8), classified in class 435, subclass 4.

XXVIII. Claims 1-10, 14 and 15, drawn to nucleic acids related to BM-HABP (SEQ ID NO: 10), vectors, host cells and methods for the expression of host cells, classified in class 536/23.1, 435/320.1, 435/325.5, and 435/69.1.

XXIX. Claims 11-12, drawn to isolated polypeptides related to BM-HABP (SEQ ID NO: 11), classified in class 530 subclass 350.

XXX. Claims 13 and 16, drawn to an antibody that binds specifically to polypeptides related to BM-HABP (SEQ ID NO: 11), classified in class 530, subclass 387.1.

XXXI. Claims 17, drawn to methods for preventing, treating, or ameliorating a medical condition using polypeptides related to BM-HABP (SEQ ID NO: 11), classified in class 514, subclass 2.

XXXII. Claim 17, drawn to methods for preventing, treating or ameliorating a medical condition using polynucleotides related to BM-HABP (SEQ ID NO: 10), classified in class 514, subclass 44.

XXXIII. Claim 18, drawn to methods of diagnosing a pathological condition by determining a mutation in polynucleotides related to BM-HABP (SEQ ID NO: 10), classified in class 435, subclass 6.

XXXIV. Claim 19, drawn to methods of diagnosing a pathological condition by determining the level of expression of polypeptides related to BM-HABP (SEQ ID NO: 11), classified in class 435, subclass 4.

XXXV. Claim 20, drawn to a method for identifying a binding partner to polypeptides related to BM-HABP (SEQ ID NO: 11), classified in class 530, subclass 412.

XXXVI. Claims 21 and 22, drawn to methods for identifying compounds capable of enhancing or inhibiting a cellular response induced by full length BM-HABP (SEQ ID NO: 11), classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

2. The claims in this case are drawn to nucleic acid, polypeptides, and methods related to four separate and distinct polypeptides WF-HABP (SEQ ID NO: 1 and 2), WF-HABP (SEQ ID NO: 4 and 5), OE-HABP, and BM-HABP. Each of these represents a distinct set of inventions. The polynucleotides are separate and distinct from one another because they encode distinct polypeptides. The polynucleotides would be expected to have domains for encoding polypeptides, different structures, different variants. The polypeptides are separate and distinct from one another as is indicated by their different sequences. They therefore are expected to have different three dimensional structures, different functions, different antibodies associated with them and different properties. Each claim in the instant specification encompasses all four of these different inventions. **For the elected group, the examiner will examine the elected claims in so far as they correspond to the elected polynucleotide or polypeptide. Amendment of the elected claims to correspond with the scope of election will be required prior to allowance.**

The separate types of claims are considered to be distinct from one another for the reasons that follow:

3. The polynucleotides (groups I, X, XIX, and XXVIII) and the polypeptides (groups II, XI, XX, and XXIX) are distinct in structure and physiochemical properties. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the compositions are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the polypeptides does not require the particular nucleic acids since the polypeptides can be isolated from natural sources or chemically synthesized.

4. The polynucleotides (groups I, X, XIX, and XXVIII) and the antibodies (groups III, XII, XXI, and XXX) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the different inventions are not disclosed as capable of use together and have different functions and different physical properties.

5. The polypeptides (groups II, XI, XX, and XXIX) and the antibodies (groups III, XII, XXI, and XXX) are distinct in structure in that the polypeptides of groups II, XI, XX, and XXIX have a different amino acid sequence than the antibodies. Furthermore, the products are utilized in different methodologies, such that the proteins may be utilized in ligand bindign assays and the antibodies may be used in therapeutic methods. Synthesis of the antibodies does not require the

particular products of the polypeptides of groups II, XI, XX, and XXIX since the antibodies can be isolated from natural sources.

6. The polynucleotides (groups I, X, XIX, and XXVIII) and the methods of prevention using polynucleotides (groups IV, XIII, XXII, and XXXI) as well as the polynucleotides (groups I, X, XIX, and XXVIII) and the methods for diagnosis using polynucleotides (groups VI, XV, XXIV, XXXIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides can be used in different methods such as nucleic acid purification methods and protein expression methods.

7. The polynucleotides (groups I, X, XIX, and XXVIII) and the methods for prevention using polypeptides (groups V, IX, XXIII, and XXXII), the methods for diagnosis using polypeptides (groups VII, XVI, XXV, and XXIV), the methods for identifying binding partners (groups VIII, XVII, XXVI and XXXV), and the methods for identifying inhibitory compounds (groups IX, XVIII, XXVII, and XXXVI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together because the polynucleotides are not required to practice the disclosed methods.

8. The polypeptides (groups II, XI, XX, and XXIX) and the methods for prevention using nucleic acids (groups IV, XIII, XXII, and XXXI), as well as the polypeptides (groups II, XI, XX,

and XXIX) and the methods for diagnosis using nucleic acids (groups VI, XV, XXIV, XXXIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together because the polypeptides are not required to practice the disclosed methods.

9. Polypeptides are related to the methods of prevention using polypeptides, the methods of diagnosis using polypeptides, the methods for the identification of binding partners and the methods of identification of inhibitory compounds all as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used in other methods such as to generating antibodies.

10. The remaining methods are unrelated. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the claims are drawn to methods which have different method steps, different goals and require different reagents.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized

divergent subject matter and because inventions I-XXXVI require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

12. A telephone call was made to Kenley Hoover on August 11, 2000 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

JEFFREY FREDMAN
PRIMARY EXAMINER

Juliet C. Einsmann
Examiner
Art Unit 1655

August 17, 2000